DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 19, 2015

Sincere Medical Device Co., Ltd.
Mr. Garfield Wang
RA Manager
Rm. 218, 2F., No. 183, Zhouzi St.
Taipei City, Taipei City 114
TAIWAN (R.O.C.)

Re: K142436
Trade/Device Name: 3S Safety Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: August 15, 2014
Received: January 23, 2015

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section_004 Indications for Use

510(k) Number (if known): K142436

Device Name: 3S SAFETY INSULIN SYRINGE

Indications for Use

The 3S Safety Insulin Syringe a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.

Prescription Use ___√____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section_005 510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date Prepared: 15. 01.2015

1. Submitter Name and Address:

Owner Name: Sincere Medical Device Co., Ltd.
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US Agent:
US Agent: Benjamin Lee.
Address: 8692 9th Street, unit 42, Rancho Cucamonga, ca 91730
TEL: 1909-985-0648

2. Submission Devices Information:

Trade/Proprietary Name: 3S Safety Insulin Syringe
Common Name: Syringe, Antistick Piston Syringe
Classification name: Piston Syringe..
Class: 2.
Panel: 80.
Product codes: MEG
Submission Type: 510(k)
Regulation Number: 880.5860

3. Predicate Devices Information:

Trade Name: InsoSAFE BakSNAP Retractable Insulin Safety Syringe
510(K) Number: K050131
Company: M.K. Meditech Co., Ltd

4. Devices Description:

The 3S Safety Insulin Syringe is an integrated needle and piston syringe with an innovative anti-needle-stick mechanism. The design incorporates the ideal features desired in a safety syringe. No special techniques are required to use the safety mechanism. The mechanism allows clear visualization of the injection site at all times. The mechanism clearly shows the needle is contained within the syringe barrel. After standard techniques for injection, the plunger is withdrawn, snapped off and used syringe is discarded into a sharps container per regulatory provision.

The 3S safety syringe with/without Needle will be available in numerous sizes and combinations between the smallest (0.3cc/ml + 31G) and the largest (1cc/ml + 27G)

5. Intended Use:

The 3S Safety Insulin Syringe a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.

6. Technological Characteristics:

Through comparisons between the submitted devices with the predicate devices as follows tables. We believe the applicant devices are substantially equivalent with the predicate devices.

Safety Syringe Comparison Table

Element of Comparison	Submission Device	Predicate Device K040545
Intended Use	The 3S Safety Insulin Syringe a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.	The InsoSAFE BakSNAP Retractable Insulin Safety Syringe a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.
Principle of Operation	Normal	Normal
Syringe Capacity	Various Sizes	Various Sizes
Nozzle Type	N.A	N.A
Lubricant for Barrel	Silicone Oil	Silicone Oil
Barrel Transparency	Transparent and Clear	Transparent and Clear
Gradations Legibility	Legible	Legible
Materials **Barrel** **Plunger** **Piston** **Needle Hub** **Needle** **Needle Sheath**	 PP PP TPE PP Stainless Steel PP	 PP PP TPE PP Stainless Steel PP
Needle Gauge and Length	Various Sizes	Various Sizes
Lubricant for Needle	Silicone Oil	Silicone Oil
Sharps Injury Prevention Features	Manual Retractable	Manual Retractable
Performances	Conforms to ISO7864 ISO8537	Conforms to ISO7864 ISO8537
Biocompatibility	Conforms to ISO10993	Conforms to ISO10993
Labeling	Meet the requirements of 21 CFR	Meet the requirements of 21

	Part 801	CFR Part 801

7. Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate device are substantially equivalent.

END